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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/517,402 | 12/07/2004 | Christopher J. Criscuolo | 2832 (203-3308) | 4034 |

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| EXAMINER |
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GETTMAN, CHRISTINA DANIELLE

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| ART UNIT | PAPER NUMBER |
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3734

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04/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/517,402 | Applicant(s) CRISCUOLO ET AL. | |
| | Examiner CHRISTINA D. GETTMAN | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23-28,32-36 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23-28,32-36 and 40-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 43, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by **Pennig** (U.S. Patent NO. 5,536,127). Pennig discloses a surgical tack having a head (ref. 2) with a drive thread (ref. 5) formed thereon, a barrel portion (ref. 1) having a tissue engaging thread (ref. 4), the distal end of the drive thread and the proximal end of the tissue engaging thread having a gap between them (see Fig. 1 below), the distal end of the drive thread and the proximal end of the tissue engaging thread being in the same plane that extends through a longitudinal axis of the barrel portion, the barrel portion having a smooth/rounded leading edge, and the head being configured to facilitate removal of the tack.

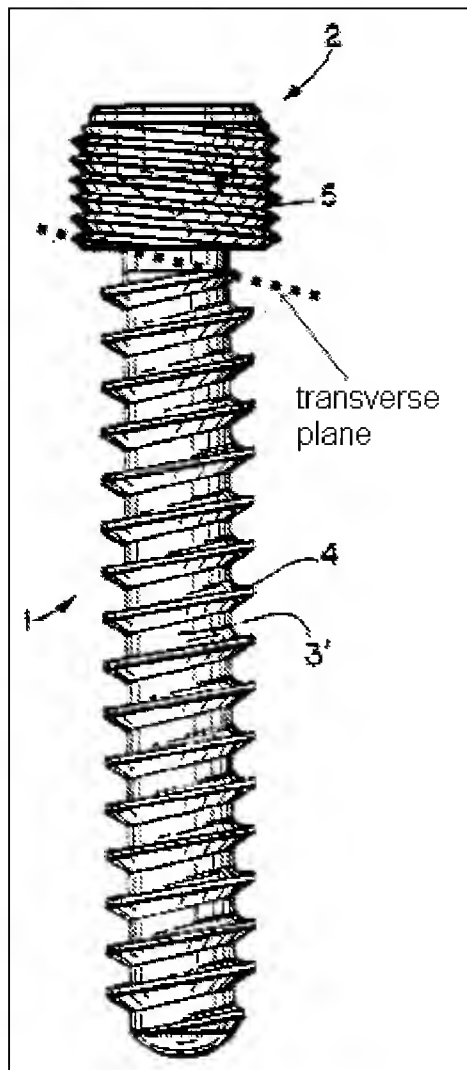


Figure 1. Screw of Pennig showing the transverse plane between the distal end of the drive thread and the proximal end of the tissue engaging thread.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **21, 23-24, 27, 32-36, and 41-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Pennig** (U.S. Patent No. 5,536,127) in view of **Augagneur et al.** (U.S. Patent No. 6,001,101). Pennig discloses a surgical tack having a head (ref. 2) with a drive thread (ref. 5) formed thereon, a barrel portion (ref. 1) having a tissue engaging thread (ref. 4), the distal end of the drive thread and the proximal end of the tissue engaging thread having a gap between them (see Fig. 1 below), the distal end of the drive thread and the proximal end of the tissue engaging thread being in the same substantially transverse plane to a longitudinal axis of the barrel portion, a transition zone between the drive thread and the tissue engaging thread, a leading edge of the drive thread being tapered (see ref. 5, Fig. 2), the maximum diameter of the drive thread being greater than the maximum diameter of the tissue engaging thread (see Fig. 2), the barrel portion having a smooth/rounded leading edge, and the head being configured to facilitate removal of the tack. Pennig does not disclose a throughbore or the threads being the same pitch. Augagneur et al. teaches a throughbore extending through the head and part of the barrel portion (ref. 30, Fig. 2) for the purpose of receiving a tool and the two threads having substantially the same pitch (see ref. 10 and 20, Fig. 1) for each of manufacturing and connection with the drive tool. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Pennig with a throughbore and the threads having the same pitch, as taught by Augagneur, in order to decrease manufacturing costs and allow for a drive tool to connect with the threads and throughbore to insert the tack into tissue.

Claim **26** is rejected under 35 U.S.C. **103(a)** as being unpatentable over **Pennig** and **Augagneur et al.**, as applied to claim 21 above, and further in view of **Huebner (U.S. Patent No. 6,030,162)**. Pennig and Augagneur et al. do not disclose a chamfered leading edge of the drive thread. Huebner does not appear to expressly disclose a chamfered drive thread on the head portion 26. However, Huebner does disclose a chamfer 80 on the leading section 24 (See Huebner figure 2; Huebner, col. 4, 63-65). Huebner also discloses, “[the] termination zone 80 [or chamfered portion] could be used on any of the screws described herein.” Huebner, col. 5, lines 6-7. This implies that the chamfered portion can be used on the trailing head portion 26. It would be obvious to apply a chamfered portion, as taught by Huebner, on the head portion of Pennig and Augagneur et al. so as to allow for smooth rotation through and insertion into shaft 146.

Claims **25** and **28** are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Pennig** and **Augagneur et al.**, as applied to claim **21** above, and further in view of **Muhling (U.S. Patent No. 5,169,400)**. Augagneur et al. discloses a throughbore but not a throughbore that has a D-shaped cross-section. Muhling claims in claim 1 “a bone screw . . . comprising an externally threaded shaft in which a tool insertion channel [or throughbore] open at the top . . . the cross-section of said insertion channel being non-circular and corresponding to the cross-section of a tool used for screwing-in said screw . . .” Muhling, claim 1. Muhling’s figures 2-5 disclose a number of different throughbore shapes. The point of Muhling’s invention is to better allow torque to be applied by the insertion tool to the screw. A D-shaped throughbore is considered within the scope of Muhling’s invention, due to the following language in claim 1, “the cross-section of said

insertion channel being non-circular and corresponding to the cross-section of a tool used for screwing-in said screw.” Id. It would be obvious to combine Muhling with Pennig and Augagneur et al. because they involve the same field of endeavor and modifying the through-bore to be D-shaped, as taught by Muhling, would better allow torque to be applied to the screw, as explained by Muhling.

Response to Arguments

Applicant's arguments with respect to claims 21, 23-28, 32-36, and 40-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kim (6,632,245) and Curtis et al. (5,464,427) disclose a screw that has a gap in the thread that where the distal end of one thread is the same transverse plane as the proximal end of another thread.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 4:30 pm (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina D Gettman/
Examiner, Art Unit 3734
571-272-3128

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731